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| Applicant | : | Kenneth J. Ruchala et al. |
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| Title | : | METHOD FOR MODIFICATION OF RADIOTHERAPY TREATMENT DELIVERY |
| TC/A.U. | : | 3737 |
| Examiner | : | James M. Kish |
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| Customer No. | : | 023409 |

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Alexandria, VA 22313-1450

## APPEAL BRIEF

Sir:

This Appeal Brief is filed with the Board of Patent Appeals and Interferences in response to the Office action dated April 29, 2010, in which the Examiner finally rejected claims 27-57, and further to the Notice of Appeal filed on July 27, 2010. This Appeal Brief is accompanied by the fee of $540.00 pursuant to 37 C.F.R. § 41.20(b)(2).

(1) Real Party in Interest

The real party in interest is TomoTherapy Incorporated, having an address at 1240 Deming Way, Madison, Wisconsin 53717.

(2) Related Appeals and Interferences

There are no prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the this appeal.

(3) <u>Status of Claims</u>

Claims 27-57 are pending and finally rejected by the Examiner. Claims 1-26 are canceled. The Applicant appeals the rejection of claims 27-57.

(4) Status of Amendments

No amendments were filed after the April 29, 2010 final Office Action.

(5) Summary of Claimed Subject Matter

(Citations in parentheses are from U.S. Patent Application Publication No. 2005/0201516).

A. Independent Claim 27

Independent claim 27 recites a method for achieving a desired dose distribution. The method includes the steps of obtaining at least one treatment planning image from a patient to determine the relative location of target and sensitive structures (See, for example, Figs. 2, 10, and 11; paras. 4, 9, and 20), preparing a treatment plan for the patient based on the at least one treatment planning image, the treatment plan including a planned dose distribution (See, for example, Figs. 2, 10, and 11; paras. 4, 6, 14, 19, and 20), obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations (See, for example, Figs. 2, 10, and 11; paras. 13, 14, 20, 50, 51, 65), comparing the at least one treatment planning image and the at least one three-dimensional image (See, for example, Figs. 2, 10, and 11; paras. 50-55, 59, 65, 76, and 78), and adjusting how the dose is received by the patient based on the comparison (See, for example, Figs. 2, 10, 11; paras. 14-15, 18-19, 24, 54-58, and 65).

B. Independent Claim 44

Independent Claim 44 recites a method of delivering radiation therapy. The method includes the steps of acquiring a first image of a region of interest in a patient (See, for example, Figs. 2, 10, and 11; paras. 4, 9, and 20), generating a plurality of radiation treatment plans for the patient based on the first image (See, for example, paras. 19-21, 23, 60), acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being at least three-dimensional and including anatomical data (See, for example, Figs. 2, 10, and 11; paras. 13, 14, 20, 50, 51, 65), and selecting one of the radiation treatment plans based at least in part on dosimetric information from the second image (See, for example, paras. 22-23, 50, 60, and 78).

C. Independent Claim 50

Independent Claim 50 recites a method of delivering radiation therapy. The method includes the steps of acquiring a first image of a patient (See, for example, Figs. 2, 10, and 11; paras. 4, 9, and 20), generating a radiation treatment plan for the patient, the radiation treatment

plan based on the first image (See, for example, Figs. 2, 10, and 11; paras. 4, 6, 14, 19, and 20), acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring (See, for example, Figs. 2, 10, and 11; paras. 13, 14, 20, 50, 51, 65), generating a contour on the second image (See, for example, Fig. 11; paras. 16, and 51), and identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour (See, for example, paras. 18, 50, 51, 58, and 65).

(6) <u>Grounds of Rejection to be Reviewed on Appeal</u>

A. Whether claims 27-57 were improperly rejected under 35 U.S.C. § 103, as being unpatentable over U.S. Patent No. 5,117,829 ("Miller") in view of U.S. Patent Application Publication No. 2002/0080915 ("Frohlich") and further in view of U.S. Patent Application Publication No. 2001/0033682 ("Robar").

(7) Argument

A. Independent Claim 27

Miller does not disclose the subject matter of amended independent Claim 27. More specifically, Miller does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

(a) obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations;

(b) comparing the at least one treatment planning image and the at least one three-dimensional image; and

(c) adjusting how the dose is received by the patient based on the comparison.

Miller is strictly related to patient alignment. Miller discloses a system and procedure for repeatedly aligning a tumor in a patient with a radiation beam of the radiation beam therapy system. Such a system and procedure allows the tumor to be positioned accurately relative to the radiation beam for any number of successive radiation treatments. Col. 1, lines 6-15. Miller utilizes image-creating techniques to provide the requisite alignment information. Further, in order to assure that the requisite alignment can be achieved over and over again, such image-creating techniques must utilize a repeatable reference image, or equivalent reference data, that provides the necessary baseline reference information for future alignments. Col. 2, lines 30-36.

As described in Miller, the patient is immobilized in a form-fitted pod, and reference radiographs (DRR) and CT scan data are acquired. Col. 2, lines 48-55. The patient is then allowed to return home. Col. 2, lines 56-57. The CT scan data is analyzed and used to prepare a treatment plan for the patient. Col. 2, lines 57-59. Once the treatment plan is finalized, the patient returns to the treatment location and is repositioned within the pod. Col. 2, line 67 – col. 3, line 1. A physical simulation of the treatment plan is then carried out to verify that the selected cancerous cells will be properly irradiated by the treatment plan. Col. 3, lines 1-4. If the physical simulation verifies that the treatment plan will properly irradiate the cancerous cells without significantly irradiating non-cancerous cells, the treatment plan is executed by irradiating the cancerous cells with the proton beam in accordance with the plan. Col. 3, lines 4-9.

During the physical simulation, the pod is positioned within the X-ray system where a physical simulation radiograph (PSR) is acquired and compared to the appropriate DRR to verify that it is essentially the same. Col. 3, line 67 – col. 4, line 6. If the comparison is

essentially the same, then the patient and pod are moved to the beam delivery system and the pod is positioned so that the radiation beam will enter the tissue volume at the desired angle. Col. 4, lines 6-10. Before actually irradiating the target tissue with the radiation beam, a further X-ray exposure of the tissue volume is made to produce yet another radiograph which is compared with the appropriate DRR and/or the PSR to verify that the correct entry angle for the beam and correct patient position have been achieved. Col. 4, lines 10-21.

As noted above, the Examiner agrees that Miller fails to disclose the limitations related to a three-dimensional image. As discussed in previous Office action responses, the radiograph image acquired by the x-ray source while the patient is positioned in the beam delivery system is only two-dimensional; not three-dimensional.

Miller is silent with respect to "obtaining at least one three-dimensional image from the patient in substantially a treatment position" because Miller is only concerned with verifying that the patient is properly aligned. Therefore, three-dimensional images are not necessary for strict alignment purposes. Miller assumes that if the patient is properly aligned based on the DRRs and PSR, the patient will receive the correct dose as prescribed in the treatment plan. However, by only using DRRs and the PSR for alignment purposes, Miller makes it clear that its system and method are not concerned about changes in the patient's anatomy, such as, for example, movement, shrinkage, or enlargement of the target, and thus how the target receives the dose.

Frohlich does not cure the deficiencies of Miller. Frohlich does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

(a) obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations;

(b) comparing the at least one treatment planning image and the at least one three-dimensional image; and

(c) adjusting how the dose is received by the patient based on the comparison.

Rather, Frohlich discloses a method of inverse planning for radiation therapy treatment including calculating a dose distribution for multiple treatment solutions and displaying the results for at least two of the treatment solutions for comparison by a treatment planner. The displaying of the two treatment solutions allows the treatment planner to select a desired one of the treatment solutions.

Frohlich focuses on the treatment planning portion of the process and does not disclose subject matter related to obtaining an image of a patient after the treatment planning process is completed and just prior to treatment delivery. Frohlich does not disclose "obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations," " comparing the at least one treatment planning image and the at least one three-dimensional image," and "adjusting how the dose is received by the patient based on the comparison."

Robar does not cure the deficiencies of Miller and Frohlich. Robar does not disclose a method for achieving a desired dose distribution comprising at least the following elements:

(a) obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations;

(b) comparing the at least one treatment planning image and the at least one three-dimensional image; and

(c) adjusting how the dose is received by the patient based on the comparison.

Rather, Robar discloses a post-treatment method of creating a three-dimensional data set based on phantom data. The method in Robar requires the delivery of treatment-level radiation to a phantom before the 3D data set can be generated. The method includes providing a plurality of radiation-sensitive films 12, which get exposed to a radiation field 17 produced by a radiosurgical system 16. The films 12 are held in a known position relative to the radiosurgery coordinate system during exposure so that the measured dose distribution can be coregistered with an intended dose distribution. The films may be processed in a suitable processor 19 to provide a series of 2D images representing the integrated dose provided in different planes through the dose distribution being studied. Paragraph 34.

In addition, Robar does not disclose obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations. The 3D data set generated in Robar does not include anatomical data and cannot include anatomical data because the data is generated by irradiating a phantom. Because Robar does not obtain a 3D image prior to treatment delivery of at least one fraction, it cannot perform dose calculations, perform the claimed comparison of the specified image, or adjust how the dose is received by the patient prior to treatment delivery.

The Examiner indicates that “upon creation of the three-dimensional dose distribution created by Robar, this image may be "spatially co-registered in treatment planning software for comparison with an intended dose distribution,” citing paragraph 45 and that “any deviations of the actual distribution from the intended dose distribution can thereby be identified before a radiosurgery treatment is delivered to a patient. The radiosurgery plan can be adjusted to correct these deviations,” citing to paragraph 46.

Applicant respectfully points out that the 3D dose distribution created by Robar utilizes dose information that was delivered to a phantom (not a patient) and reconstructed from 2D images rather than a 3D image of the patient prior to treatment delivery. The comparison performed in Robar compares post-delivery data to pre-delivery data and cannot include any patient anatomical data, such as changes in the patient anatomy that may have occurred between the time of treatment planning and the date of treatment delivery. In contrast, the subject matter of Claim 27 specifies comparing pre-delivery data (e.g., data from the treatment plan) to other pre-delivery data (e.g., a 3D image taken prior to treatment delivery) both of which include patient anatomical data.

Furthermore, the three references cannot be combined. The method of Robar requires the delivery of radiation before the 3D dose distribution can be generated and then compared to pre-delivery data in order to adjust the plan if necessary, whereas Miller is more concerned with patient alignment with respect to the machine. Robar uses the data to compare actual dose distribution to an intended dose distribution to adjust a dose to be delivered, whereas Miller compares images to obtain proper registration of the patient. There is no indication that Miller is interested in dose distribution data as a way to align the patient prior to treatment delivery.

In addition, since the 3D data set is generated by irradiation of the phantom in Robar, it is apparent that Robar is concerned only about dose delivery from the radiosurgery machine (that is, only concerned about machine performance) and whether there will be any deviations between the phantom dose delivery and the intended dose delivery to the patient. The 3D data set that gets generated in Robar does not include anatomical data, therefore Robar does not appear to consider patient anatomical changes with respect to the planning image and how the dose is going to be received by the patient due to those changes. Robar uses a phantom to determine if there will be any discrepancies in machine delivery performance without any reference to the patient and thus any dosimetric information derived from the 3D data set in Robar is based on assumptions about the patient, rather than being based on patient-specific information. As noted in paragraph 6 of Robar, it is necessary to be able to measure the actual

volumetric dose distribution provided by a radiosurgery system apparatus so as to ensure that the apparatus is functioning properly and is producing the predicted dose distribution.

Because Miller and Robar are focused on very different aspects of treatment planning and preparation for treatment delivery, it would require impermissible hindsight to combine these two references as suggested by the Examiner.

For at least these reasons, Miller, Frohlich, and Robar do not disclose the subject matter of Claim 27. Accordingly, withdrawal of the 35 U.S.C. §103(a) rejection of claim 27 is therefore respectfully requested.

B. Dependent Claims 28-43

Claims 28-43 each ultimately depend from claim 27, and are allowable based upon independent claim 27 and upon other features and elements of claims 28-43 not discussed herein. Withdrawal of the 35 U.S.C. §103(a) rejection of claims 28-43 is therefore respectfully requested.

C. Independent Claim 44

Miller does not disclose the subject matter of amended independent Claim 44. More specifically, Miller does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) generating a plurality of radiation treatment plans for the patient based on the first image;

(b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data; and

(c) selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image.

As noted above, the Examiner agrees that Miller fails to disclose the limitations related to a three-dimensional image. As discussed in previous Office action responses, the radiograph image acquired by the x-ray source while the patient is positioned in the beam delivery system is only two-dimensional; not three-dimensional.

Miller is silent with respect to "obtaining at least one three-dimensional image from the patient in substantially a treatment position" because Miller is only concerned with verifying that the patient is properly aligned. Therefore, three-dimensional images are not necessary for strict alignment purposes. Miller assumes that if the patient is properly aligned based on the DRRs

and PSR, the patient will receive the correct dose as prescribed in the treatment plan. However, by only using DRRs and the PSR for alignment purposes, Miller makes it clear that its system and method are not concerned about changes in the patient's anatomy, such as, for example, movement, shrinkage, or enlargement of the target, and thus how the target receives the dose.

Frohlich does not cure the deficiencies of Miller. Frohlich does not disclose a method of delivering radiation therapy comprising at least the following elements:

(b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data; and

(c) selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image.

As noted above, Frohlich focuses on the treatment planning portion of the process and does not disclose subject matter related to obtaining an image of a patient after the treatment planning process is completed and just prior to treatment delivery. Frohlich does not disclose "acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data" and "selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image."

Robar does not cure the deficiencies of Miller and Frohlich. Robar does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) generating a plurality of radiation treatment plans for the patient based on the first image;

(b) acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data; and

(c) selecting one of the radiation treatment plans based on a position of the region of interest in the second image and dosimetric information in the second image.

As noted above, Robar discloses a post-treatment method of creating a three-dimensional data set based on phantom data. The method in Robar requires the delivery of treatment-level radiation to a phantom before the 3D data set can be generated. The method includes providing a plurality of radiation-sensitive films 12, which get exposed to a radiation field 17 produced by a radiosurgical system 16. The films 12 are held in a known position relative to the radiosurgery coordinate system during exposure so that the measured dose

distribution can be coregistered with an intended dose distribution. The films may be processed in a suitable processor 19 to provide a series of 2D images representing the integrated dose provided in different planes through the dose distribution being studied. Paragraph 34.

In addition, Robar does not disclose acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being three-dimensional and including anatomical data. The 3D data set generated in Robar does not include anatomical data and cannot because the data is generated by irradiating a phantom.

Furthermore, the three references cannot be combined. The method of Robar requires the delivery of radiation before the 3D dose distribution can be generated and then compared to pre-delivery data in order to adjust the plan if necessary, whereas Miller is more concerned with patient alignment with respect to the machine. Robar uses the data to compare actual dose distribution to an intended dose distribution to adjust a dose to be delivered, whereas Miller compares images to obtain proper registration of the patient. There is no indication that Miller is interested in dose distribution data as a way to align the patient prior to treatment delivery.

In addition, since the 3D data set generated by irradiation of the phantom in Robar, it is apparent that Robar is concerned only about dose delivery from the radiosurgery machine (that is, only concerned about machine performance) and whether there will be any deviations between the phantom dose delivery and the intended dose delivery to the patient. The 3D data set that gets generated in Robar does not include anatomical data, therefore Robar does not appear to consider patient anatomical changes with respect to the planning image and how the dose is going to be received by the patient due to those changes. Robar uses a phantom to determine if there will be any discrepancies in machine delivery performance without any reference to the patient and thus any dosimetric information derived from the 3D data set in Robar is based on assumptions about the patient, rather than being based on patient-specific information. As noted in paragraph 6 of Robar, it is necessary to be able to measure the actual volumetric dose distribution provided by a radiosurgery system apparatus so as to ensure that the apparatus is functioning properly and is producing the predicted dose distribution.

Because Miller and Robar are focused on very different aspects of treatment planning and preparation for treatment delivery, it would require impermissible hindsight to combine these two references, as suggested by the Examiner.

For at least these reasons, Miller, Frohlich, and Robar do not disclose the subject matter of Claim 44. Accordingly, withdrawal of the 35 U.S.C. §103(a) rejection of claim 44 is therefore respectfully requested.

D. Dependent Claims 45-49

Claims 45-49 each ultimately depend from claim 44, and are allowable based upon independent claim 44 and upon other features and elements of claims 45-49 not discussed herein. Withdrawal of the 35 U.S.C. §103(a) rejection of claims 45-49 is therefore respectfully requested.

E. Independent Claim 50

Miller does not disclose the subject matter of independent Claim 50. More specifically, Miller does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring;

(b) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

As noted above, the Examiner agrees that Miller fails to disclose the limitations related to a three-dimensional image. As discussed in previous Office action responses, the radiograph image acquired by the x-ray source while the patient is positioned in the beam delivery system is only two-dimensional; not three-dimensional. As also previously discussed, a two-dimensional x-ray image is not suitable for three-dimensional contouring.

Miller is silent with respect to "obtaining at least one three-dimensional image from the patient in substantially a treatment position" because Miller is only concerned with verifying that the patient is properly aligned. Therefore, three-dimensional images are not necessary for strict alignment purposes. Miller assumes that if the patient is properly aligned based on the DRRs and PSR, the patient will receive the correct dose as prescribed in the treatment plan. However, by only using DRRs and the PSR for alignment purposes, Miller makes it clear that its system and method are not concerned about changes in the patient's anatomy, such as, for example, movement, shrinkage, or enlargement of the target, and thus how the target receives the dose.

Frohlich does not cure the deficiencies of Miller. Frohlich does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring, and

(b) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

As noted above, Frohlich focuses on the treatment planning portion of the process and does not disclose subject matter related to obtaining an image of a patient after the treatment planning process is completed and just prior to treatment delivery. Frohlich does not disclose "acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring" and "identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour."

Robar does not cure the deficiencies of Miller and Frohlich. Robar does not disclose a method of delivering radiation therapy comprising at least the following elements:

(a) acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring, and

(b) identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

As noted above, Robar discloses a post-treatment method of creating a three-dimensional data set based on phantom data (not a patient). The method in Robar requires the delivery of treatment-level radiation to a phantom before the 3D data set can be generated. The method includes providing a plurality of radiation-sensitive films 12, which get exposed to a radiation field 17 produced by a radiosurgical system 16. The films 12 are held in a known position relative to the radiosurgery coordinate system during exposure so that the measured dose distribution can be coregistered with an intended dose distribution. The films may be processed in a suitable processor 19 to provide a series of 2D images representing the integrated dose provided in different planes through the dose distribution being studied. Paragraph 34.

In addition, Robar does not disclose acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring. There is no discussion in Robar regarding contouring.

Furthermore, the three references cannot be combined. The method of Robar requires the delivery of radiation before the 3D dose distribution can be generated and then compared to pre-delivery data in order to adjust the plan if necessary, whereas Miller is more concerned with patient alignment with respect to the machine. Robar uses the data to compare actual dose distribution to an intended dose distribution to adjust a dose to be delivered, whereas Miller compares images to obtain proper registration of the patient. There is no indication that Miller is interested in dose distribution data as a way to align the patient prior to treatment delivery.

In addition, since the 3D data set generated by irradiation of the phantom in Robar, it is apparent that Robar is concerned only about dose delivery from the radiosurgery machine (that is, only concerned about machine performance) and whether there will be any deviations between the phantom dose delivery and the intended dose delivery to the patient. The 3D data set that gets generated in Robar does not include anatomical data, therefore Robar does not appear to consider patient anatomical changes with respect to the planning image and how the dose is going to be received by the patient due to those changes. Robar uses a phantom to determine if there will be any discrepancies in machine delivery performance without any reference to the patient and thus any dosimetric information derived from the 3D data set in Robar is based on assumptions about the patient, rather than being based on patient-specific information. As noted in paragraph 6 of Robar, it is necessary to be able to measure the actual volumetric dose distribution provided by a radiosurgery system apparatus so as to ensure that the apparatus is functioning properly and is producing the predicted dose distribution.

Because Miller and Robar are focused on very different aspects of treatment planning and preparation for treatment delivery, it would require impermissible hindsight to combine these two references, as suggested by the Examiner.

For at least these reasons, Miller, Frohlich, and Robar do not disclose the subject matter of Claim 50. Accordingly, withdrawal of the 35 U.S.C. §103(a) rejection of claim 50 is therefore respectfully requested.

F. Dependent Claims 51-57

Claims 51-57 each ultimately depend from claim 50, and are allowable based upon independent claim 50 and upon other features and elements of claims 51-57 not discussed herein. Withdrawal of the 35 U.S.C. §103(a) rejection of claims 51-57 is therefore respectfully requested.

## **Conclusion**

In view of the foregoing, reversal of the final rejection of Claims 27-57 and allowance of Claims 27-57 are respectfully requested.

Respectfully submitted,

/julie a. haut/

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(8) Claims Appendix

27. A method for achieving a desired dose distribution comprising:

obtaining at least one treatment planning image from a patient to determine the relative location of target and sensitive structures;

preparing a treatment plan for the patient based on the at least one treatment planning image, the treatment plan including a planned dose distribution;

obtaining at least one three-dimensional image from the patient in substantially a treatment position, the three-dimensional image including anatomical data and being used for volumetric dose calculations;

comparing the at least one treatment planning image and the at least one three-dimensional image; and

adjusting how the dose is received by the patient based on the comparison.

28. The method of claim 27 wherein the planned dose distribution for the patient is based on the treatment plan.

29. The method of claim 27 further comprising repositioning the planned dose distribution for the patient based on the at least one three-dimensional image of the patient in substantially a treatment position.

30. The method of claim 27 further comprising modifying the treatment plan and the planned dose distribution.

31. The method of claim 27 further comprising adjusting patient position to better position patient's internal anatomy relative to the planned dose distribution.

32. The method of claim 28, wherein the planned dose distribution is based on the at least one three-dimensional image of the patient in substantially a treatment position.

33. The method of claim 27, wherein the planned dose distribution is modified to take into account changes in patient position and/or changes in patient anatomy.

34. The method of claim 27, further comprising selecting a treatment plan from a plurality of preexisting plans for the patient based on the three-dimensional image acquired from the patient at the time of treatment delivery.

35. The method of claim 34, wherein multiple plans created with objective functions are used for treatment delivery.

36. The method of claim 27, wherein objective functions and weightings are adjusted to fine-tune treatment delivery.

37. The method of claim 27, wherein objective function weights are learned.

38. The method of claim 27, wherein the output of the dose calculation is utilized to move the patient, modify treatment delivery, or some combination of the two.

39. The method of claim 27, further comprising generating contours on one of the target and sensitive structures by one of manual contouring, automated contouring, deformable fusion, template-based automatic contouring, and a combination thereof.

40. The method of claim 27, wherein adjusting how the dose is received by the patient includes repositioning the patient to improve the dose distribution.

41. The method of claim 27, wherein the images of the patient are obtained using one of non-quantitative CT, MRI, PET, SPECT, ultrasound, transmission imaging, fluoroscopy, and RF-based localization.

42. The method of claim 38, wherein the treatment plan includes initially available images and related treatment plans and images obtained subsequent to initial planning.

43. The method of claim 27, wherein adjusting how the dose is received by the patient includes utilizing one of image information, contour information, dose-volume histograms, and dosimetric information to reposition the patient.

44. A method of delivering radiation therapy, the method comprising:

acquiring a first image of a region of interest in a patient;

generating a plurality of radiation treatment plans for the patient based on the first image;

acquiring a second image of the region of interest while the patient is in substantially a treatment position, the second image being at least three-dimensional and including anatomical data; and

selecting one of the radiation treatment plans based at least in part on dosimetric information from the second image.

45. The method of claim 44 further comprising generating a different radiation treatment plan based on a different position of the region of interest than the position of the region of interest in the first image and the second image.

46. The method of claim 44 further comprising comparing a position of the region of interest in the first image to a position of the region of interest in the second image.

47. The method of claim 44 wherein each of the radiation treatment plans includes a contour defining a margin around the region of interest based on the position of the region of interest in the first image.

48. The method of claim 44 wherein the second image is adequate for dose calculations.

50. A method of delivering radiation therapy, the method comprising:

acquiring a first image of a patient;

generating a radiation treatment plan for the patient, the radiation treatment plan based on the first image;

acquiring a second image of the patient substantially in a treatment position, the second image being three-dimensional and suitable for three-dimensional contouring;

generating a contour on the second image; and

identifying a patient position with respect to a radiation delivery device based on dosimetric information and the contour.

51. The method of claim 50 wherein the second image is suitable for dose calculations.

52. The method of claim 51 wherein identifying a patient position is further based on the dose calculations.

53. The method of claim 50 further comprising generating a plurality of treatment plans based at least in part on the first image.

54. The method of claim 53 further comprising selecting one of the treatment plans for delivery to the patient, the selected treatment plan based on a desired patient position.

55. The method of claim 50 wherein the dosimetric information is determined from the first image.

56. The method of claim 50 wherein the dosimetric information is determined from the second image.

57. The method of claim 50 wherein the dosimetric information is determined from a combination of the first image and the second image.

(9) Evidence Appendix

Appellant has not submitted evidence pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 or any other evidence entered by the examiner and relied upon in this appeal.

(10) Related Proceedings Appendix

As noted above in Section 2 of this Appeal Brief, there are no related appeals or interference proceedings related to this application.